

REMARKS

Entry of the above amendments and reconsideration of this application are respectfully requested. Upon entry of the amendments, this application will contain claims 1-19, 42-49, and 51-72 pending and under consideration. The Office Action objects to the Declaration and sets out several claim rejections. Each of these matters is addressed in below in the sequence given in the Office Action. It is believed that each objection and rejection is comprehensively addressed and overcome. Therefore, reconsideration and allowance of this application are requested.

I. Objection to the Declaration

The objection to the Declaration as unsigned and thus defective is noted. Applicant submits herewith the signed copy of the Declaration. Entry and approval are solicited.

II. Rejections under 35 U.S.C. §112

Claims 1-19, 42, 44-47, and 56-57 stand rejected under 35 USC §112, second paragraph. As a first matter, the Action asserts that the recitation of "at least about" renders the claims indefinite. This rejection is respectfully traversed. In arguing this aspect of the rejection, the Action states that "it is unclear what the metes and bounds are of 'at least about'". It is beyond question that the phrase "at least" is clear in the claims, as this is a commonly used expression. The basis of this rejection must therefore center upon the term "about". However, long-accepted and controlling legal precedent clearly establishes that use of the term "about" does not render a claim indefinite. This is evident not only in the case law but also in the multitude of patents issued and continuing to issue using this claim term. As such, it is submitted that this rejection is without support, and its withdrawal is solicited.

The Action rejects claim 13 because "porous particulate mineral" lacks antecedent basis. In response, the term "porous" has been deleted, leaving "particulate mineral". This latter term has direct antecedent basis.

Claims 44-47 stand rejected because the limitation "device" in line 1 has insufficient antecedent basis. In response, claim 44 has been amended to be dependent upon independent claim 43, which provides the necessary antecedent basis. A similar amendment has been entered in claim 45, and claims 46 and 47 now depend from claims 45 and 46, respectively. Direct antecedent basis now exists. In any event, even with their prior dependencies, it is submitted that one skilled in the art would understand the claims.

Claim 46 stands rejected because the limitation "ceramic material" lacks antecedent basis. In response, claim 46 has been amended to be dependent upon claim 45, and the

word "material" has been deleted. The resulting term "ceramic" has direct antecedent basis in claim 45.

Claim 47 stands rejected because "calcium phosphate ceramic" has insufficient antecedent basis. In response, claim 47 has been amended to be dependent upon claim 46, which provides the necessary antecedent basis.

In view of the foregoing, withdrawal of the subject rejection of claims 1-19, 42, 44-47 and 56-57 is solicited.

Claims 3, 16, 54-55, and 63-64 stand rejected under 35 USC § 112, second paragraph, based upon an assertion that they are indefinite. The basis for this rejection pertains to the use of the terms "LIM mineralization protein" and "BMP". It is believed that the claims are clear in their original form. Nonetheless, in order to expedite the prosecution of this application, claim 3, which has the first instance of "bone morphogenetic protein", has been amended to add "(BMP)" immediately after the term. No amendment has been entered in respect of LIM mineralization protein (LMP), since this is the term by which the relevant proteins are known. As is understood in the art, they are so named for their inclusion of a characteristic structural motif known as the LIM domain. For additional information on the subject, the Examiner may refer to WO9906563, which is cited in the present application at page 10, line 4.

In view of the foregoing, withdrawal of the subject rejection of claims 3, 16, 54-55, and 63-64 is solicited.

III. Rejections under 35 U.S.C. § 102

Introduction

To support a rejection for anticipation under 35 U.S.C. § 102, the Patent Office must demonstrate that each and every element set forth in the claimed combination is taught in the applied reference. Any shortfall in a reference to teach every element negates a proper rejection under this statute. Moreover, the MPEP contains guidance concerning assessing anticipation in a case where a claim includes a range (MPEP 2131.03). Specifically, the MPEP provides that it is not sufficient for anticipation that the prior art teaches a range within, overlapping, or touching the claim range. Rather, anticipation can only be made out where, in the facts of the particular case, the claimed range is taught with sufficient specificity. As specific guidance, MPEP 2131.03 directs that:

If the claims are directed to a narrow range, the reference teaches a broad range, and there is evidence of unexpected results within the claimed narrow range, depending upon the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to

constitute an anticipation of the claims. The unexpected results may also render the claims unobvious.

Analysis

An analysis of the present case reveals that the Office Action fails to set forth reasons why the claimed elements are taught in the applied references with sufficient specificity, nor are any such reasons apparent from the references. Accordingly, the claims are not anticipated by the applied references, and the rejections should be withdrawn.

Turning now to the specific rejections, claims 42, 48, 51-53, and 61-62 stand rejected based upon the allegation that they are anticipated by U.S. Patent No. 4,888,366 (Chu). This rejection is respectfully traversed.

Claim 42 requires a carrier and an osteogenic factor, wherein the carrier has a resorbable sponge matrix with particulate mineral embedded in the matrix and "present in an amount constituting at least about 95% by weight of said carrier". The remainder of these claims require a resorbable sponge matrix with particulate biocompatible mineral embedded in the matrix and comprising 97% to 99% by weight of the device. In making the rejection for anticipation, the Office Action notes mineral content ranges of 60%-98% and collagen content ranges of 2%-40% taught for the devices of Chu. The Office Action then concludes, completely summarily, that this constitutes an anticipation of the claimed ranges. No analysis is provided as to why these broad ranges taught by Chu teach the narrowly claimed ranges with sufficient specificity. Nor is any account taken in the Office Action of the express teachings in the application supporting the unexpected results obtained with the applicants claimed sponge materials, or the problems that they solve.

As explained in the present application at page 5:

A particular feature of the present application relates to the discovery that the inclusion of an osteogenic factor, especially an osteoblast- and osteoclast-stimulating osteogenic factor, in a resorbable sponge composition causes a substantially accelerated resorption of the sponge. This rapid resorption can diminish or eliminate the capacity of the sponge composition to effectively stimulate and support new bone formation in a void filled with the sponge composition. This is particularly the case in primates, including humans, in which the rate of new bone formation is relatively slow. Objects of the present invention are to provide osteogenic sponge compositions effective for the induction of bone growth in mammals, particularly primates, including humans, and related methods and devices.

Continuing at pag 7, the application explains:

In accordance with th present inv ntion, it has been found that the incorporation of an effective inductive amount of an osteogenic factor, such as a bon morphogen tic protein (BMP), stimulates osteoclasts to such a

level that a porous resorbable carrier is quickly resorbed and, in the absence of a high mineral component in the composition, causes the performance of the composition to suffer in some cases to the extent that observation of substantial bone ingrowth is sporadic. Although such non-mineralized sponge compositions may be highly effective for repair of bone defects in lower animals, such as mice, that have a faster bone growth rate, they are less effective in large animals such as primates, including humans.

For the above reasons, the claimed invention presently under consideration includes narrowly defined ranges that require very high mineral contents (95%+ or 97% to 99%) and low collagen contents (e.g. 1% to 3%). Neither these extreme ranges, nor their unexpected advantages, nor the problems they solve, are taught by the broad ranges expressed in Chu. Furthermore, it is noteworthy that every preparative example in Chu falls outside these ranges.

In view of the foregoing, and the express guidance of the MPEP, Chu fails to anticipate 42, 48, 51-53, and 61-62. Withdrawal of the subject rejection is therefore solicited.

Claims 43, 45-47, 57-59, and 60 stand rejected under 35 USC § 102(b) based upon an assertion that they are anticipated by U.S. Patent No. 5,123,925 (Smestad). This rejection is also respectfully traversed, for reasons similar to those above concerning the Chu reference.

The above-listed claims require the extreme ranges of 1%-3% collagen and 97%-99% particulate mineral, providing the advantages and addressing the problems discussed in the application and quoted above. As noted in the Office Action, Smestad teaches ranges similar to those taught in Chu (which is understandable, as the two patents are in a related priority line). Again, after quoting these ranges, the Action summarily concludes that Smestad anticipates the above-listed claims. For reasons much the same as those discussed above with respect to Chu, this fails to establish a case of anticipation by Smestad. Withdrawal of the rejection of claims 43, 45-47, 57-59, and 60 is thus solicited.

In summary, the references cited in the rejections under 35 U.S.C. § 102 do not teach the claimed ranges with sufficient specificity for anticipation. Accordingly, withdrawal of each such rejection is solicited.

IV. Rejections under 35 U.S.C. § 103

Introduction

To support a proper rejection under 35 U.S.C. § 103, the burden is upon the Patent Office to establish a *prima facie* case of obviousness. To establish such a *prima facie* case, all of the claim limitations must be taught or suggested by the prior art. See, MPEP 2143.03

and *In re Royka*, 180 USPQ 580 (CCPA 1974). "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure." MPEP 2143, emphasis added, citing *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991). On the subject of what constitutes sufficient motivation to support a combination of references, MPEP 2143.01 directs that "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art suggests the desirability of the combination" (citing *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990). Similarly, MPEP 2143.01 notes that "A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill of the art at the time the claimed invention was made' because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references" (citing *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) and *In re Kotzab*, 55 USPQ2d 1313 (Fed Cir. 2000)).

Analysis

An analysis of the present case reveals that the Office Action fails to establish a *prima facie* case that any of the claims is obvious. The Action proposes reference combinations without explanation as to why one skilled in the art would be positively motivated to make the combinations. In many instances, the rejections are tantamount to an assertion that the references "could be combined" or that certain combinations were "within the ordinary skill in the art", which are improper to support a proper rejection under 35 U.S.C. § 103 as expressly noted in the above-cited passages of the MPEP and the relevant case law. Accordingly, the claims at issue are not obvious over the proposed combinations of references, and the subject rejections should be withdrawn.

Turning now to the specific obviousness rejections, claims 1-15 and 18-19 stand rejected under 35 USC § 103(a) based upon an assertion that they are unpatentable over Chu in view of U.S. Patent No. 5,573,771 (Geistlich). This rejection is respectfully traversed.

As disclosed in the instant application including the passages cited above, a feature of the present application relates to the discovery that the inclusion of osteogenic factors such as BMPs in resorbable sponge compositions causes a substantially accelerated resorption of the sponge, which can diminish or eliminate the observation of effective induction of bone growth in the void occupied by the sponge. The invention includes embodiments that address this phenomenon by the incorporation of high levels of mineral in the sponge composition that prove to provide an effective, lasting scaffold for bone growth,

particularly in primates, even in the presence and under the influence of such osteogenic factors.

Neither Chu nor Geistlich teach anything with respect to the problem solved by the present claimed invention, nor do they teach the elements claimed invention or their advantages in solving that problem. Furthermore, on the subject of their combination, the Action posits that a desire for "optimization" would have motivated the combination of the Geistlich teaching as to particle size with Chu. This appears tantamount to finding motivation because the change would be "within the ordinary skill in the art", which does not support a proper rejection (see above-cited MPEP passages). Moreover, upon what basis or functional parameter disclosed in the references would this "optimization" occur? The Action proposes none. It is therefore submitted that this rationale for the combination fails.

As a basis for combining the Geistlich teaching of bone particles with Chu, the Action states that the bone particles naturally occur to the body and thus would present a decreased chance of infection or rejection when implanted. However, the teachings of Geistlich pertain to the use of animal bone, which would carry risks of rejection and infection. No evidence or explanation is given as to why the animal bone particles of Geistlich would be expected to decrease the chances of infection or rejection when implanted in the body as compared to synthetic materials. This rationale for the combination thus also fails.

Additional arguments for combining Geistlich with Chu are set forth in the Action at pages 9 and 10. However, in each case, no sufficient motivation is present. Rather, the Action simply states that the combination would have been "obvious" or a matter of "routine experimentation". Such statements are again tantamount to saying that the references "could have been" combined or that their combination "would have been within the ordinary skill in the art", and do not fulfill the need for a showing as to why the references, considered alone, positively motivate the claimed combination.

For the above reasons, it is submitted that the rejection of claims 1-15 and 18-19 as being unpatentable over Chu in view of Geistlich is overcome. Its withdrawal is solicited.

Claims 16 and 17 stand rejected under 35 USC § 103(a) based upon an allegation that they are unpatentable over Chu in view of Geistlich, and further in view of U.S. Patent No. 5,231,169 (Constantz). This rejection is traversed.

Claims 16 and 17 ultimately depend upon claim 1. As discussed above, the proposed combination of Chu in view of Geistlich fails to motivate the skilled artisan to carry out the invention of claim 1. Furthermore, Constantz adds nothing to provide such motivation. For these reasons at the last, it is submitted that this rejection overcomes and

should be withdrawn. Furthermore, the Office Action fails to explain the necessary motivation to add Constantz to Chu and Geistlich. Instead, the Office Action merely states that this would be obvious as a matter of "routine experimentation". As discussed above, such generalizations do not provide the necessary motivation to support combinations. Reconsideration and withdrawal of the rejections of claims 16 and 17 are therefore solicited.

Claim 44 stands rejected under 35 USC § 103(a) upon an assertion that it is unpatentable over Smestad in view of Geistlich. This rejection is respectfully traversed because the Office Action fails to set forth sufficient motivation for combining Geistlich with Smestad. In attempting to support the combination, the Office Action states that the bone particles naturally occur to the body and thus would present a decreased chance of infection or rejection when implanted. However, as noted above, the teachings of Geistlich pertain to the use of animal bone, which would carry risks of rejection and infection, and no evidence or reasoned explanation is given as to why the particles of Geistlich would be expected to decrease the chances of infection or rejection when implanted in the body as compared to a synthetic material. Withdrawal of this rejection of claim 44 is thus solicited.

Claim 40 stands rejected under 35 USC § 103(a) based upon an allegation that it is unpatentable over Chu, Geistlich, Constantz, McKay, and Smestad, and further in view of Michelson. Thus, a combination of the teachings of six references has been mosaiced together to arrive at the limitations contained in claim 49. In the Action's statement of this rejection, the propriety of combining Chu, Geistlich, Constantz, McKay, and Smestad is presumed. However, as discussed above, there is insufficient motivation to do so. Further, with regard to the additional reference, Michelson, the Office Action simply states "it would have been obvious to one of ordinary skill at the time of the claimed invention to fill the spinal infusion implant of Michelson with an osteogenic composition. Thus, one would have been motivated by Michelson to fill the spinal fusion implant of Michelson with the osteogenic composition of Geistlich, Constantz, McKay, and Smestad...". There is no explanation of motivation here. At best, this is only an assertion that the reference teachings "could have been combined". It is thus respectfully submitted that this rejection is unsupported, and should be withdrawn.

Claims 54-55 and 63-64 stand rejected under 35 USC § 103(a) based upon an allegation that they are unpatentable over Chu in view of Constantz. In attempted support for this combination, the Office Action states "it would have been obvious to one of ordinary skill at the time of the claimed invention to use BMP-2 as the osteogenic factors as a matter of routine experimentation." As noted in the above-quoted MPEP passages and discussion, this does not provide sufficient motivation to support a rejection under 35 USC § 103. The

fact that the references could be combined is insufficient. The references, when considered by themselves, must support the conclusion that they would be combined by one of ordinary skill in the art. In this case, they do not. Accordingly, withdrawal of the rejection is solicited.

Claim 56 stands rejected under 35 USC § 103(a) based upon an allegation that it is unpatentable over Chu in view of Geistlich. It is submitted that this rejection is overcome, at the least, for reasons similar to those discussed above. Chu fails to teach the advantages obtained by the inventive combination or problems solved, and fails to specifically teach the combination claimed including the extremely high range of mineral and low range of collagen. Further, the Office Action argues only that the skilled artisan would be motivated to the combination for purposes of "optimization". As noted above, this does not provide positive motivation as required to support the obviousness rejection. Moreover, the gist of the teachings of Geistlich appear to pertain to impregnating bone materials with certain other materials to strengthen them, and not to the optimization of particle sizes for incorporation into sponge implants as claimed. As such, it is submitted that this rejection is overcome, and its withdrawal is solicited.

In summary, the obviousness rejections set forth in the Office Action lack proper support. Accordingly, they should be withdrawn.

New claims 65-72 have been added to the application, as dependent claims. They are believed to be allowable, at the least, for the same reasons that their parent claims are allowable. Favorable consideration of these new claims is thus solicited. Support for claims 65-69 is found at page 3, lines 8-11. Support for claims 70-72 is found throughout the application and in the original claim set. It is believed that no new claim fees are due, due to the prior cancellation of a greater number of claims than those that have been since added. In particular 23 claims were canceled in the Amendment dated April 14, 2003, and 22 claims have since been added, with two independent claims canceled and two added, and the rest dependent claims. However, should any new claim fees be due, the Patent Office is authorized to charge them to Deposit Account No. 23-3030.

For the foregoing reasons, it is submitted that this application is in condition for allowance containing claims 1-19, 42-49, and 51-72. Prompt action to that end is solicited.

The Examiner is invited to please contact the undersigned attorney by telephone if there are any questions about this submission or if there is any matter that might be addressed in that fashion to expedite the allowance of this application. In this regard, should the Examiner believe that any basis for objection or rejection remains, the

undersigned would welcome the opportunity to personally interview the Examiner to expedite a resolution of the case.

Respectfully submitted,

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